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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/800,448 | 03/05/2001 | Santu Bandyopadhyay | A34065 | 2808 |

21003 7590 04/12/2007
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NEW YORK, NY 10112-4498

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| EXAMINER |
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EWOLDT, GERALD R

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| ART UNIT | PAPER NUMBER |
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1644

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/12/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/800,448

Applicant(s)

BANDYOPADHYAY ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 2/22/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment remarks have been entered.

2. Claims 1-38 have been canceled.
New Claims 39-64 are pending.

3. Upon reconsideration, and in view of the cancellation of all previously pending claims and the submission of new claims, all previous rejections have been withdrawn.

4. The following are new grounds for rejection.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39-64 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An *in vitro* method for producing mature dendritic Langerhans cells, said method comprising:

a. culturing peripheral blood monocytes in a medium containing mammalian platelets;

b. incubating the culture at about 30°C to about 40°C for a period sufficient to enable formation of mature dendritic

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Langerhans cells; and

c. analyzing the cultured cells for the appearance of dendritic processes and markers associated with dendritic Langerhans cells,

wherein the presence of dendritic morphology and processes and reactivity to anti-CD 1a, anti-CD80, and anti-CD83 monoclonal antibodies indicates growth of mature dendritic Langerhans cells (Claim 39).

B) The method of claim 39 (or 52) further comprising analyzing the mature dendritic Langerhans cells produced by flow cytometry. (Claims 48 and 61).

C) The method of claim 39 wherein the platelets are from rat and peripheral blood monocytes are from mouse (Claim 41).

D) An *in vitro* method for producing mature dendritic Langerhans cells, said method comprising:

a. culturing a preparation of bone marrow cells in a medium containing mammalian platelets;

b. incubating the culture at about 30°C to about 40°C for a period sufficient to enable formation of mature dendritic Langerhans cells; and

c. analyzing the cultured cells for the appearance of dendritic processes and markers associated with dendritic Langerhans cells,

wherein a subpopulation of the culture differentiates into dendritic Langerhans cells, and wherein the presence of dendritic morphology and processes and reactivity to anti-CD 1a, anti-CD80, and anti-CD83 monoclonal antibodies indicates growth of mature dendritic Langerhans cells (Claim 52).

Applicant cites no specific support for any of the new claims and none has been found.

Regarding A), the specification does not disclose (a) the culturing of any monocyte with any mammalian platelet. Nor does the specification support (b) a temperature range of "about" 30°C to "about" 40°C. Nor does the specification support the generic "analyzing" step of (c). Neither does the specification support the final "wherein" clause.

Regarding B), the specification does not disclose the generic flow cytometry analysis of the claimed method.

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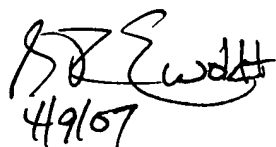
Regarding C), the specification does not disclose the culture of rat platelets with mouse blood monocytes.

Regarding D), the specification does not disclose (a) the culturing of any bone marrow cell with any mammalian platelet. Nor does the specification support (b) a temperature range of "about" 30°C to "about" 40°C. Nor does the specification support the generic "analyzing" step of (c). Neither does the specification support the final "wherein" clause.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://www.pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600